Emtriva: New Formulation and Labeling Changes

On September 28, 2005, The Food and Drug Administration approved EMTRIVA (emtricitabine) Oral Solution 10 mg/mL. The approval of this Oral Solution formulation allows for dosing recommendations in pediatric patients. EMTRIVA is now indicated in combination with other antiretroviral agents, for the treatment of HIV-1 infection in patients over three months of age.

In addition the following changes to the label were made: (Please refer to the attached pdf document for specific details)

Clinical Pharmacology Section
Pharmacokinetic data in pediatrics, renal impairment information and results from a drug-drug interaction study with zidovudine were included.

Indications and Usage
The indication was expanded to include patients over three months of age.

Precautions
Addition of zidovudine to the drug interactions section, addition of the immune reconstitution syndrome section, updated carcinogenicity data and pediatric use statements were included.

Adverse Reactions
This section was updated to include data in pediatric patients.

Dosage and Administration
This section was revised to include dosing information in pediatric patients with the oral solution and capsule formulations. In addition, dosing information for the oral solution for adult patients was included. A new table was added to include dose adjustment information in adults with renal impairment for the capsule and oral solution formulations.

How Supplied
Data on storage conditions for the Oral Solution were included.

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